EUROPEAN
COMMISSION

Bruxelles, 28.8.2015
C(2015)6119 (final) corr

COMMISSION IMPLEMENTING DECISION

of 28.8.2015

correcting Decision C(2015)4366 (final) amending the marketing authorisation granted by Decision C(2013)4019(final) for "Xtandi - enzalutamide", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Astellas Pharma Europe B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinions of the European Medicines Agency, formulated on 23 April 2015 and on 21 May 2015 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The marketing authorisation granted by Decision C(2013)4019(final) for "Xtandi-enzalutamide", a medicinal product for human use has been amended by Decision C(2015)3677 and by Decision C(2015)4366.

(2) The Commission has been made aware that changes introduced in Annexes I and IIIB of the Decision C(2015)3677 were not in Annexes I and IIIB of Decision C(2015)4366. This Decision rectifies therefore Decision C(2015)4366 (final) by correcting accordingly Annexes I and IIIB. Consequently, it should apply retroactively from the date of notification of that Decision.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 334, 12.12.2008, p. 7.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2015)4366 (final) is corrected as follows:

Annexes I and IIIB shall be replaced by the text set out in Annexes I and IIIB to this Decision.

Article 2

This Decision applies from 24 June 2015.

Article 3

This Decision is addressed to Astellas Pharma Europe B.V., Sylviusweg 62, NL-2333 BE Leiden, Nederland.

Done at Brussels, 28.8.2015

For the Commission

Ladislav MIKO
Acting Director-General